REMARKS

The Office Action dated October 6, 2004 presents the examination of claims 1-14. Claims 11 and 12 are canceled without prejudice or disclaimer of the subject matter recited therein. Claims 1-10 and 13-14 are amended. Support for subject matter added to the claims is particularly pointed out in the table below. No new matter is inserted into the application.

Phrase	**Claims**	**Non-limiting examples of support in the Specification**
"for assaying target antigen or target antibody present in a serum component or a blood plasma component of a whole blood sample"	1, 13	Page 7, lines 12-16
"which are sensitized with an antigen or antibody"	1, 13	Page 8, lines 6-7 and 16-20
"have different size than that of blood cells"	1, 13	Page 8, lines 10-15
"resulting in an immune agglutination reaction mixture comprising agglutinated insoluble carrier particles and unagglutinated insoluble carrier particles"	1, 13	Page 4, lines 31-32; page 8, lines 26-32; page 10, lines 19-24
"first" and "second" threshold values	1, 13	Page 12, lines 22-28 and Figure 3
"present in the whole blood sample"	3, 4, 5	Page 14, lines 20-22; page 16, lines 14-19
"the scattered light"	13	Page 9, lines 1-8; page 11, lines 15-31
"curve showing a relationship between the degree of agglutination and the concentration of the target antigen or target antibody"	14	Page 10, line 31 to page 11, line 14; page 14, lines 13-19

Drawings (Page 2, Paragraph 2 of the Office Action)

The Examiner notes that the drawings are informal, but that formal drawings are not necessary until the application is allowed. Applicants will submit formal drawings upon allowance.

Information Disclosure Statement (Page 2, Paragraph 3 of the Office Action)

The Examiner objects to the Information Disclosure Statement filed on April 8, 2002 for failure to comply with 37 C.F.R. § 1.98(a)(3). The Examiner requests a concise explanation of the relevance of Etsuro SHINKAI et al., *Sysmex J.* (1997) 20(1):77-78. Applicants submit herewith under separate cover an Information Disclosure Statement including a verified translation of SHINKAI et al. Thus, the objection is overcome.

Rejection under 35 U.S.C. § 112, second paragraph (Pages 2-6, Paragraph 4 of the Office Action)

The Examiner rejects claims 1-14 under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. Claims 11 and 12 are canceled, thus rendering rejection thereof moot. Applicants respectfully traverse the rejection of the pending claims. Reconsideration and withdrawal of the instant rejection are respectfully requested.

The Examiner asserts that claim 1 is vague and indefinite because it is allegedly unclear what structural and functional cooperative relationship exists between the sensitized insoluble carrier particles in step a) and the unagglutinated particles in step b). Claim 1 is amended to clarify that the immune agglutination reaction comprises the agglutinated insoluble carrier particles and the unagglutinated insoluble carrier particles. This amendment is non-narrowing in nature and serves only to clarify claim language.

The Examiner asserts that claim 1 is ambiguous because it is allegedly unclear what elements are present in the whole blood sample. Claim 1 is amended to recite that the target antigen or target antibody is present in a serum component or a blood plasma component of a whole blood sample. This amendment is non-narrowing in nature and serves only to clarify claim language. In particular, this amendment clarifies that the inventive method assays target antigen or target antibody.

The Examiner asserts that the scope of the term "sensitized" is unclear. Applicants respectfully submit that "sensitized" when used in the context of immunoassay is not a subjective term. Instead, "sensitized" is a term of art meaning, "immunized." See, page 8, lines 6-9 and 16-20 of the specification. In other words, the insoluble carrier particles are immunized with antigen or antibody

by any method known in the art, such as physical absorption, chemical binding, etc.

The Examiner states that the comparison of "sensitized insoluble carrier particles smaller than erythrocytes" is confusing. Claim 1 is amended to recite that the insoluble carrier particles "have a different size than that of blood cells." As disclosed in the specification, such as on page 8, lines 10-15, the carrier particles suitably have a size that allows them to be distinguished from the blood cells. This amendment is non-narrowing in nature and serves only to clarify claim language.

The Examiner asserts that it is unclear how setting a 1) threshold value for distinguishing unagglutinated particles and agglutinated particles and 2) threshold value for distinguishing agglutinated particles and blood cells can be performed, with regard to the intensity of scattered light. The Examiner makes similar rejections to claims 3 and 13. As noted above, claim 1 is amended to recite that the immunoassay assays target antigen or target antibody present in a whole blood sample. A first threshold value is set for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles, and a second threshold value is set for distinguishing the agglutinated insoluble carrier particles from blood cells with regard to

intensity of the scattered light. This amendment is non-narrowing in nature and serves only to clarify claim language.

The Examiner also rejects claims 2-12 and 14 for minor misspellings and errors in antecedent basis. The claims are amended in order to correct these informalities.

The Examiner asserts that the recitation of "antigen" in claim 2 is confusing because it encompasses "cell surface antigens" which the Examiner asserts would affect the calculation of the calibration line. The Examiner makes similar rejections to claims 4 and 5 over the recitation of "the concentration of the antigen or antibody in the whole blood." Applicants respectfully disagree. Claim 1, as amended, recites that the inventive immunoassay assays target antigen or target antibody present in a whole blood sample. The target antigen therefore, does not encompass cell surface antigens. This amendment is non-narrowing in nature and serves only to clarify claim language.

The Examiner asserts that the recitation of "calibration line produced beforehand" in claim 2 lacks proper antecedent basis. Claim 2, as amended, no longer recites this phrase. Instead, claim 2 recites that a calibration curve is produced which shows the relationship between the degree of agglutination and the concentration of target antigen or antibody. This amendment is

non-narrowing in nature and serves only to resolve issues relating to antecedent basis.

Finally, the Examiner asserts that claims 13 and 14 are vague and indefinite because the structural and functional cooperative relationship between "light signal" and "scattered light generated" is unclear. Claim 13 is amended to recite that the photo acceptance unit detects the generated scattered light, and the signal processing means converts the scattered light into an electrical signal. Again, this amendment is non-narrowing in nature and serves only to clarify claim language.

Based on the above, Applicants respectfully submit that the claims particularly point out and distinctly claim the subject matter, which is the present invention. Withdrawal of the instant rejection is therefore respectfully requested.

Rejection under 35 U.S.C. § 102(e) (Pages 6-7, Paragraph 5 of the Office Action)

The Examiner rejects claims 1, 2, and 9-12 under 35 U.S.C. § 102(e) for allegedly being anticipated by Moskowitz et al. (US 2001/0046685 A1). Claims 11 and 12 are canceled, thus rendering rejection thereof moot. Applicants respectfully traverse the rejection of the pending claims. Reconsideration and withdrawal of the instant rejection are respectfully requested.

In the immunoassay of the present invention, and as recited in claim 1, a first threshold value is set for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles, and a second threshold value is set for distinguishing the agglutinated soluble carrier particles from blood cells with regard to intensity of the scattered light. The unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells from the scattered lights detected above can be counted with reference to the first and second threshold values.

Moskowitz et al. disclose an immunoassay to measure platelet count by use of an antigen directed to fibrinogen. However, Moskowitz et al. do not disclose the first and second threshold values as recited in the claims. Moskowitz et al. do not disclose that the unagglutinated insoluble carrier particles can be distinguished from agglutinated insoluble carrier particles, or that the agglutinated insoluble carrier particles can be distinguished from blood cells. Finally, Moskowitz et al. do not disclose counting the particles or blood cells by using the above two set threshold values.

For these reasons, Moskowitz et al. fail to disclose each and every limitation of the instant claims. As such, Moskowitz et al. fail to anticipate the present invention under 35 U.S.C. § 102(e).

Withdrawal of the instant rejection is therefore respectfully requested.

Rejection under 35 U.S.C. § 102(b) (Pages 7-8, Paragraph 6 of the Office Action)

The Examiner rejects claims 13 and 14 under 35 U.S.C. § 102(b) for allegedly being anticipated by Kosako '714 (U.S. Patent 5,527,714). Applicants respectfully traverse. Reconsideration and withdrawal of the instant rejection are requested.

Using the immunoassay apparatus recited in claim 13, the skilled artisan can perform a highly accurate immunoassay on a whole blood sample without the need to hemolyze the whole blood sample or separate serum therefrom, as described on page 4, lines 21-24, of the specification. On the other hand, Kosako '714 does not disclose an immunoassay apparatus wherein an immunoassay can be carried out with a whole blood sample, as acknowledged by the Examiner on page 9 of the Office Action. Moreover, Kosako '714 fails to disclose the other elements of claim 13, i.e., a laser, a photo acceptance unit, a signal processing means, and a data processing means, which are comprised in the immunoassay apparatus of the present invention.

For these reasons, Kosako '714 fail to disclose each and every limitation of the instant claims. As such, Kosako '714 fail to anticipate the present invention under 35 U.S.C. § 102(e).

Withdrawal of the instant rejection is therefore respectfully requested.

Rejection under 35 U.S.C. § 103(a) (Pages 8-10, Paragraphs 7-8 of the Office Action)

Kosako '714 in view of Moskowitz et al.

The Examiner rejects claims 1-4 and 9-12 under 35 U.S.C. § 103(a) for allegedly being obvious over Kosako '714 in view of Moskowitz et al. Claims 11 and 12 are canceled, thus rendering rejection thereof moot. Applicants respectfully traverse the rejection of the pending claims. Reconsideration and withdrawal of the instant rejection are respectfully requested.

Kosako '714 fails to disclose an immunoassay which can be performed on a whole blood sample. The Examiner, however, argues that it would be obvious to substitute the whole blood sample of Moskowitz et al. with the sample utilized by Kosako '714 to produce the present invention. Applicants respectfully disagree.

The immunoassay of the present invention can be used to perform a highly accurate immunoassay on a whole blood sample, as stated above. In order to perform the immunoassay on a whole blood sample, a first threshold value is set for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles, and a second threshold value is set for distinguishing

the agglutinated soluble carrier particles from blood cells with regard to intensity of the scattered light. The unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells from the scattered lights detected above can be counted with reference to the first and second threshold values.

Kosako '714 in view of Moskowitz et al., either alone or in combination, fail to disclose the first and second threshold values as recited in the claims. The cited references further do not disclose that the unagglutinated insoluble carrier particles can be distinguished from agglutinated insoluble carrier particles, or that the agglutinated insoluble carrier particles can be distinguished from blood cells. Finally, Kosako '714 in view of Moskowitz et al. do not disclose counting the particles or blood cells by using the above two set threshold values.

For these reasons, the instant claims are not obvious under 35 U.S.C. § 103(a) over Kosako '714 in view of Moskowitz et al. Withdrawal of the instant rejection is therefore respectfully requested.

Kosako '714 in view of Moskowitz et al. and further in view of Steel '351

The Examiner also rejects claim 8 under 35 U.S.C. § 103(a) for allegedly being obvious over Kosako '714 in view of Moskowitz et al. and further in view of Steel '351 (WO 98/20351). Applicants respectfully traverse. Reconsideration and withdrawal of the instant rejection are respectfully requested.

The Examiner relies on Steel '351 to teach forward scattered light. However, as noted above, Kosako '714 in view of Moskowitz et al. fail to render the claims of the present application obvious. Steel '351 merely teaches forward scattered light and does not make up for the deficiencies of Kosako '714 and Moskowitz et al. As such, the instant claims are not obvious under 35 U.S.C. § 103(a) over Kosako '714 in view of Moskowitz et al. and further in view of Steel '351. Withdrawal of the instant rejection is therefore respectfully requested.

Conclusion

Applicants respectfully submit that the above remarks and/or amendments fully address and overcome the outstanding rejections and objections. For the foregoing reasons, Applicants respectfully request the Examiner to withdraw all of the outstanding rejections and objections, and to issue a Notice of Allowance indicating the

patentability of the present claims. Early and favorable action of the merits of the present application is thereby respectfully requested.

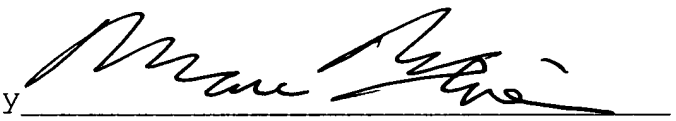
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to 37 C.F.R. 1.17 and 1.36(a), the Applicants respectfully petition for a one (1) month extension of time for filing a reply in connection with the present application, and the required fee of $120.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 
Marc S. Weiner, #32,181

MSW/KLR:trb

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

Attachment(s): Information Disclosure Statement (w/attachments)